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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,091	01/16/2004	Thomas L. Cantor	532212000624	2110

25225 7590 10/23/2006

MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,091	CANTOR ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-107* is/are pending in the application.

4a) Of the above claim(s) *47-68 and 98-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/18/04; 9/29/06;* 5/6/04
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 7/31/2006 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-46 are cancelled.
2. Claims 47-107 are added to the instant application.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
   - I. Claims 47-68, drawn to a method of producing antibodies to human PTH, classified in class 436, subclass 536.
   - II. Claims 69-97, drawn to PTH antibodies, classified in class 530, subclass 389.2.
   - III. Claims 98-107, drawn to a method for detecting bioactive PTH, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I, III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The products recited in inventions II can be practiced by another materially different process other than the purposes recited in inventions I and III, such as isolation or purification of the PTH from samples.

3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention I is for producing antibodies to a PTH, whereas invention III is for detection of the PTH in a sample. Each invention has different modes of operation, functions or different effects

(MPEP § 806.04, MPEP § 808.01). Therefore, it is deemed proper that inventions I and III are unrelated.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the search required for one group is not required for the other, and the search for one group is not required for another group, therefore restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Mr. Chen on 10/11/2006 a provisional election was made with traverse to prosecute the invention of group II, claims 69-97. Affirmation of this election must be made by applicant in replying to this Office action. Claims 47-68 and 98-107 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Currently, claims 69-97 are under examination. Claims 47-68 and 98-107 are withdrawn from further consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 69-80, 83-85, 88-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al. (J. Clin. Investigation 1974 Vol. 54, page 1382 ; applicant submitted IDS reference).

With respect to claims 69, 80, 88, 89, 91, 92, 95, Fischer et al. teach isolated antibodies that recognizes and binds to the bioactive, three dimensional epitope, i.e. 1-12 or 1-34, of parathyroid hormone (PTH) (See Abstract).

With respect to claims 70, 75, the antibodies used by Fischer et al. recognize the amino terminus of human PTH. Surpa.

With respect to claims 72-77, 85, 94, the antibody recognizing 1-12 is within the recited range from 1-13 of SEQ ID No. 1 of the human PTH starting from amino-terminal Ser in position 1 to Lys in the position 13. surpa.

With respect to claims 79, the antibodies inherently can reduce the adenylate cyclase activity of PTH because the position of the epitope of PTH. Surpa.

With respect to claim 86, Fischer et al. teach immunization of animals with the PTH peptides and recovering antibodies from the animals and isolating the PTH antibodies (See Method).

With respect to claims 84, 93, 96, Fischer et al. teach using isotopes to label antibodies for detection purpose (See Methods).

3. Claims 69-80, 83-85, 88-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Magerlein (I) et al. (Pharmaceutical Sciences 1994, Vol. 2, page 117-194 Abstract ; applicant submitted IDS reference)).

With respect to claims 69, 75-76, 80-81, 88, 89, 91, 92, 95, Magerlein et al. (I) teach an isolated antibody that recognizes and binds to the bioactive, three dimensional epitope, i.e. 1-5 or 1-34 , of parathyroid hormone (PTH) (See Abstract).

With respect to claims 70, 75, the antibodies used by Magerlein et al. (I) recognize the amino terminus of human PTH. Surpa.

With respect to claims 72-74, 76-77, 85, 94, the antibody recognizing 1-5 is within the recited range from 1-13 of SEQ ID No. 1 of the human PTH starting from amino-terminal Ser in position 1 to Lys in the position 13. surpa.

With respect to claims 79, the antibodies inherently can reduce the adenylate cyclase activity of PTH because the position of the epitope of PTH. Surpa.

With respect to claims 84, 93, 96, Magerlein et al. (I) teach two-sites immunoassay (e.g. labeling antibodies) for detection purpose. Supra.

4. Claims 69-81, 83-85, 88-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Magerlein et al. (II) (Arzneim-Forsch/Drug Res 1998 Vol. 48, page 783-787; applicant submitted IDS reference)).

With respect to claims 69, 75, 80-81, 88, 89, 91, 92, 95, Magerlein et al. (II) teach an isolated antibody that recognizes and binds to the bioactive, three dimensional epitope, i.e. 1-10 , of parathyroid hormone (PTH) (See Abstract).

With respect to claims 70, the antibodies used by Magerlein et al. (II) recognize the amino terminus of human PTH. Surpa.

With respect to claims 72-74, 76-77, 85, 94, the antibody recognizing 1-10 is within the recited range from 1-13 of SEQ ID No. 1 of the human PTH starting from amino-terminal Ser in position 1 to Lys in the position 13. surpa.

With respect to claims 79, the antibodies inherently can reduce the adenylate cyclase activity of PTH because the position of the epitope of PTH. Surpa.

With respect to claims 84, 93, 96, Magerlein et al. (I) teach ELISA immunoassay (e.g. labeling antibodies) for detection purpose (See Methods).

5. Claims 69-81, 83-85, 88-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Colford et al. (Endocrine Society 79th Meeting , June 11-14 1997 Minneapolis, Minnesota; applicant submitted IDS reference)).

With respect to claims 69, 75, 80-81, 88, 89, 91, 92, 95, Colford et al. teach an isolated antibody that recognizes and binds to the bioactive, three dimensional epitope, i.e. 1-7 or 1-14 of parathyroid hormone (PTH) (See Abstract).

With respect to claims 70, the antibodies used by Colford et al. recognize the amino terminus of human PTH. Surpa.

With respect to claims 72-74, 76-77, 85, 94, the antibody recognizing 1-10 is within the recited range from 1-13 of SEQ ID No. 1 of the human PTH starting from amino-terminal Ser in position 1 to Lys in the position 13. surpa.

With respect to claims 79, the antibodies inherently can reduce the adenylate cyclase activity of PTH because the position of the epitope of PTH. Surpa.

With respect to claims 84, 93, 96, Colford et al. teach ELISA immunoassay (e.g. labeling antibodies) for detection purpose (See Abstract).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 82, 86-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Margelein (I-II) or Colford et al. in view of Gotschlich et al. (US 5545553).

The references of Margelein (I-II) or Colford et al. have been discussed but do not explicitly teach using humanized antibody.

Gotschlich et al. teach using humanized antibody providing the advantage of inducing much less immune response than xenogenic antibodies, in particular an allergic response (Col. 20, line 14-20).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Margelein (I-II) or Colford et al. with the humanized antibody as taught by Gotschlich et al. in order to reduce allergic response in the immunoassay of patients.

With respect to claim 86-87, Gotschlich et al. teach using the keyhole limpet hemocyanin as a linker carrier to produce antibody (Col. 19, line 47-52). It is a well-known and widely practiced procedure to immunize animals and recovering antibodies from the immunized animals. Surpa.

9. Claim 97 isrejected under 35 U.S.C. 103(a) as being unpatentable over either Margelein (I-II) or Colford et al. in view of Chang et al. (US 4824777).

The references of Margelein (I-II) or Colford et al. have been discussed but do not explicitly teach using acridinium ester as the label for detection purpose.

Chang et al. teach using variety of means to label antibody, including enzymatic, fluorogenic, radiometric, chemiluminescent. One of the compound taught by Chang et al. is acridinium ester (Col. 3, line 1-10).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Margelein (I-II) or Colford et al. with the alternative label compound such as acridinium ester as taught by Chang et al. because using different alternative label means to label antibody is well-known in the art, and it merely involves routine practice.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641

October 12, 2006

LONG V. LE 10/13/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600